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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,091	02/01/2002	Marshall D. Crew	PC23132A	7361

152 7590 04/29/2005

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,091	CREW ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37.CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks, all filed 01/14/05. Claims 1-20 and 22-25 are pending.

Claim Rejections - 35 USC § 112

1. Claims 1, 6 and 13 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for quinoline cholesteryl ester and carboxymethyl ethyl cellulose and polyoxyethylene-polyoxypropylene block copolymers as the concentration enhancing polymers, does not reasonably provide enablement for all cholesteryl ester protein inhibitors and all concentration enhancing polymers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

2. Applicants traverse the rejection on the grounds that HPMCAS (Examples 1, 4, 7), HPMCP (Example 2), PVP (Example 3), CAT (Example 4), CAP (Example 5), HPMC (Example 6) are concentration enhancing polymers and as such concentration enhancing polymers are well supported in the disclosure and that Examiner provided no basis for the rejection. Furthermore, applicants state that the burden is on the Examiner to provide evidence to establish a prima facie case to support the rejection. "Applicants' specification must otherwise be taken as presumptively enabling.

3. Applicants' arguments, see remarks, filed 01/14, with respect to concentration enhancing polymers have been fully considered and are persuasive (In re Marzocchi and Horton). However, it is respectfully noted that carboxymethyl ethyl cellulose and polyoxyethylene-polyoxypropylene block copolymers are described as concentration enhancing polymers in the

specification (paragraph [0022] of the published specification). The specification does not state HPMCAS, HPMCP, PVP, CAT, CAP, HPMC as concentration enhancing polymers. Since the list is not exhaustive, it is respectfully suggested that the claims recite the disclosed concentration enhancing polymers in a Markush language. For example, concentration enhancing polymers are cellulosic or non-cellulosic, neutral or ionizable in aqueous solution, concentration enhancing polymers can also be blends of polymer and can be single species of polymer; concentration enhancing polymer are ionizable cellulosic polymers, non-ionizable cellulosic polymers, ionizable non-cellulosic polymers, non-ionizable non-cellulosic polymers, neutralized acidic polymers and blends (see US 6,763,607).

4. Applicants' arguments filed 01/14/05 with respect to cholesteryl ester transfer protein inhibitor have been fully considered but they are not persuasive. Paragraph [0021] of the published application provides (4'S)-5'-(4-fluorophenyl)-6'-[(S)-fluoro[4-(trifluoromethyl)phenyl]methyl-]-3',4'-dihydro-7'-(1-methylethyl)-spiro[cyclobutane-1,2'(1'H)-naphthalen]- -4'-ol and (2R)-3-[[3-(4-chloro-3-ethylphenoxy)phenyl][[3-(1,1,2,2-tetrafl-uoroethoxy)phenyl]methyl]amino]-1,1,1-trifluoro-2-propanol, and pharmaceutically acceptable forms thereof as cholesteryl ester transfer protein inhibitor. These are the CETP's that are enabled and the scope of protection sought by the recited cholesteryl ester transfer protein inhibitor is not commensurate with the scope of the disclosed cholesteryl ester transfer protein inhibitor. Therefore, it is respectfully suggested that the enabled CETP's be claimed using a Markush type claim.

Claim Objections

Claims 20-24 were method claims that failed to limit the method of claims 1, 6 or 13. However, claims 20 and 22-24 are amended to depend from claim 25, a product of claims 1-18. The objection to claims 20-24 is thus withdrawn in light of the amendment to claims 20 and 22-24.

Claim Rejections - 35 USC § 102

5. Claims 1-5, 13-20 and 22-25 remain rejected under 35 U.S.C. 102(b) as being anticipated by Miyajima et al. (US 4,983,593).

Applicants traverse the rejection on the grounds that NZ-105, also known as efonidipine is not a CETP inhibitor and the CETP inhibitors elevate plasma lipid levels (e.g. HDL) and lower certain other plasma lipid levels (LDL) and accordingly treat diseases that are affected by low levels of HDL and high levels of LDL.

6. Applicants' arguments filed 01/14/05 have been fully considered but they are not persuasive.

Kitahara discloses the reduction of VLDL by efonidipine and Toyoda discusses the benefit of NZ-105 (efonidipine) on atherosclerosis as admitted by applicants. It is known in the art that VLDL and low HDL are associated with increased risk for atherosclerosis and coronary artery disease (see teaching reference, US 6,369,075, column 4, lines 25-34). Thus the NZ-105 of Miyajima is a CETP. The instant claims do not exclude NZ-105 (efonidipine).

Claim Rejections - 35 USC § 103

7. Claims 6-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Miyajima et al. (US 4,983,593) in view of Nakamichi et al. (US 5,456,923).

Applicants state that neither Miyajima nor Nakamichi discloses CETP inhibitors ands that Examiner has used hindsight reasoning in the rejection under 35 USC 103.

8. Applicants' arguments filed 01/14/05 have been fully considered but they are not persuasive.

It is shown, in the response to the argument traversing the anticipation of the designated claims by Miyajima, that Miyajima's NZ-105 is a CETP. Nakamichi is relied upon for the use of twin-screw extruder to form solid dispersion of mixtures of cardiovascular system drug and concentration enhancing polymers. The missing element of the method of Miyajima is disclosed in Nakamichi and properly combined since the process of Nakamichi uses twin-screw extruder to form solid dispersion of mixtures of cardiovascular system drug and HPMCAS or AQOAT, which are concentration-enhancing polymers. NZ-105 or efonidipine is a cardiovascular system drug ands HPMCAS is a concentration enhancing polymer.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action.. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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